Government Response to the Lord's Science & Technology Select Committee Report into Nanotechnologies and Food

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HOUSE OF LORDS SCIENCE AND TECHNOLOGY SELECT COMMITTEE REPORT ON NANOTECHNOLOGIES AND FOOD

RESPONSE TO RECOMMENDATIONS AND CONCLUSIONS

Introduction

The House of Lords Science and Technology Select Committee published its Report on Nanotechnologies and Food on 8 January 2010. This Memorandum sets out the Government's response to the conclusions and recommendations in that report.

The Food Standards Agency has coordinated this response, which also includes contributions from the Department for Business, Innovation and Skills and the Department for Environment, Food and Rural Affairs.

The Government welcomes the Committee's report, which describes the current situation regarding the application of nanotechnologies in relation to food and identifies issues that need to be addressed by the Government and other stakeholders. The report focuses primarily on nanomaterials which may be added to food, either directly as ingredients or indirectly by migration from food packaging and other food contact materials and makes a number of significant recommendations. The Government recognises the importance of this developing area and this response sets out the actions that will be taken to address the points raised by the Committee's report.

Nanotechnologies in the food sector

Encouraging the commercialisation of nanotechnologies in the food sector

Recommendation 1. We recommend that, as part of their commitment to gain a better understanding of the needs of United Kingdom industry sectors likely to use nanotechnologies, the Government should pay specific attention to identifying the needs of the food industry and make provision for meeting those needs in their 2010 national strategy (paragraph 3.36).

BIS undertook a nanotechnology evidence gathering exercise which led to a group of Knowledge Transfer Networks using the Innovation and Growth Team (IGT) methodology to form a Nanotechnology Mini-IGT which included a Steering and Review Group of 90 industrialist and academics. The Mini-IGT ran for four and a half months and launched its report "Nanotechnology: a UK Industry View" on 14th January 2010. The report provides a coherent bottom up approach to industry's needs and identifies areas where it thinks government should pay particular attention. Nanotechnology and food is one of the many potential application areas covered in the Mini-IGT report which fed into the 2010 UK national strategy for nanotechnology. Some of the actions in the strategy will have significant crossover into the nanotechnology and food sector.

Recommendation 2. We recommend that Government should take steps to ensure the establishment of research collaborations between industry, academia and other relevant bodies at the pre-competitive stage in order to promote the translation of basic research into commercially viable applications of nanotechnologies in the food sector (paragraph 3.37).

The Technology Strategy Board already has in place mechanisms for supporting pre-competitive collaborative research between industry, academia and other relevant bodies so that developments from the research base can be transferred to industry for commercial exploitation. It is also working to ensure that the research funded by Research Councils UK under their Nanotechnology Grand Challenges is pulled through by industry for exploitation. Over the next 3 years the Technology Strategy Board will be looking to develop nanotechnologies in the food sector as part of its wider technology inspired activity through collaborative research and development, feasibility study competitions, and through knowledge transfer partnership activity, as well as potential for SBRI activity. The Technology Strategy Board is also developing an innovation platform looking at the challenge of sustainable agrifood, and this will provide opportunities for nanoscale technologies that can help to solve the challenges raised in this area.

Recommendation 3. We recommend that the Technology Strategy Board reviews the state of the commercialisation of nanotechnologies in the food sector. As part of this review it should suggest mechanisms for improving the effectiveness of current knowledge transfer systems (paragraph 3.38).

The Technology Strategy Board has published strategies in the Biosciences and Nanoscale technologies. These state the significant market opportunities for UK business in the food sector, including those that use novel technical approaches such as nanoscale engineering in food packaging. Investments have been made in innovative projects within the food

manufacturing sector through the TSB's collaborative R&D competitions. The Technology Strategy Board provides Knowledge Transfer support principally through the Biosciences and Nanotechnology Knowledge Transfer Networks (KTNs). The Biosciences KTN has four priority areas one of which is food. In addition, the NanoFood Subject Interest Group (SIG) is a joint knowledge transfer activity between the Biosciences and Nanotechnology KTNs and also includes the Leatherhead Food Research. Some SIGs are formed and driven by their members with the support of one or more KTNs but SIGs can also be created to perform specific, time-limited activities that are funded by a non-KTN source. The Technology Strategy Board will work with the KTN programme to review the food sector related interest groups that are already existent and will identify the most appropriate way to review the sector.

Recommendation 4. We recommend that the Technology Strategy Board includes consideration of the role that nanotechnologies may play in helping the food industry meet societal challenges, such as obesity and waste, in its strategies for promoting nanoscale technologies and biosciences, and that the Technology Strategy Board proposes ways of supporting the development and commercialisation of these technologies (paragraph 3.49).

The Technology Strategy Board has as published strategies for Biosciences, Environmental Sustainability, Medicines and Healthcare as well as Nanoscale technologies. The opportunities for the food industry to meet societal challenges have been stated and funding opportunities have been made available for projects that meet these challenges, such as the recent Technology-inspired competition. Current opportunities for funding support include the Knowledge Transfer Partnerships programme and future funding through collaborative R&D competitions is likely.

Health and Safety

Filling the knowledge gaps

Recommendation 5. We recommend that the Research Councils should establish more pro-active forms of funding to encourage the submission of research bids to address the severe shortfalls in research required for risk assessment of nanomaterials as set out in the EMERGNANO report, and ensure that submissions are reviewed by a committee with appropriate expertise in this field (paragraph 4.43).

The Government accepts this recommendation. Both the EPSRC and MRC have recently used signpost or highlight notices to stimulate and encourage their communities to research in this important area. In addition, the Research Councils have recently carried out an independent evaluation of their nanoscience portfolio.

The MRC nanotoxicology 'highlight' notice has focused on encouraging proposals which investigate the health impact of nanoparticles *in vivo* or aim to validate *in vitro* tests against *in vivo* models with a particular emphasis on studies addressing the mechanisms of toxicity. To date four projects have been funded.

The EPSRC 'signpost' notice in nanotoxicology and metrology has concentrated on methods to detect and characterise the effects of nano particles within the body (or the environment)

and their effects human health. This has resulted in £1.3M award being made to universities of Swansea and Leeds in Summer 2009.

NERC has provided £500K over 3 years to help support the establishment of FENAC (Facility for the Environmental Nanoparticle Analysis and Characterisation) at the University of Birmingham. The work carried out at this centre is essential to underpin research in ecotoxicology, groundwater chemistry/transport and human health.

The Research Councils carried out an extensive, independent evaluation of their nanoscience portfolio during September 2009. The report is currently being finalised and is due for publication in early 2010. A number of recommendations were made during this process; including in relation to the risks associated with nanotechnologies that the cross-council programme, Nanoscience through Engineering to Application, is currently seeking to address.

The Research Councils are committed to involving subject experts in the peer review of all proposals and intend to keep the portfolio under review to ensure appropriate and relevant nanotechnology research is funded. They will reflect on their portfolio in the light of the Committee's recommendation.

Recommendation 6. We recommend that, as part of any strategy to address the research shortfalls identified in the EMERGNANO report, the Government should ensure that specific research is focused on the gut and the other knowledge gaps we have identified above (paragraphs 4.18–4.27) with relevance to the risk assessment of nanomaterials in food or food contact materials (paragraph 4.44)

As part of its recent review of the UK's nanotechnology research priorities, the Nanotechnologies Research Co-ordination Group has highlighted the need for further assessment of likely exposure to nanomaterials through ingestion. This forms the basis for one of the Government's revised nanotechnology Research Objectives. Supporting this work, the Health Protection Agency has already launched its National Nanotoxicology Research Centre in Chilton in late 2009 following an initial investment of £1m. The Centre has been equipped to perform toxicological studies on the effects of nanoparticles when absorbed into the body via ingestion and will be undertaking studies to investigate the uptake of nanomaterials from the intestinal tract. (as well as inhalation and dermal uptake). Early work to be undertaken at the Centre will investigate the biokinetics of nanomaterials. Discussions are also ongoing regarding the setting up a collaborative programme of work on gut uptake of nanomaterials.

Further, the Food Standards Agency (FSA) has commissioned two projects, which started in early 2010, to investigate the oral toxicokinetics of relevant nanoparticles. One project will examine an *in vitro* absorption model and human toxicokinetics whilst the other will use a different *in vitro* absorption model and animal toxicokinetics. In its oral evidence to the Committee, the Agency was unable reveal the number of applications that were being evaluated following its call for research proposals in this area, as this information was regarded as commercially confidential while negotiations with the applicants were under

way. As the contracts have now been agreed, the Agency can inform the Committee that two proposals were received and modified versions of both are now being funded.

Recommendation 7. We recommend that the Government ensure that a breakdown of annual public spending on nanotechnology-related environmental, health and safety research within the United Kingdom is compiled and available when the five-year review of its progress against the 2004 Royal Society and Royal Academy of Engineering report is carried out (paragraph 4.48).

The Government remains committed to developing the evidence base in support of environment health and safety research into nanotechnologies. As this work progresses we will maintain an overview account of public research expenditure.

Recommendation 8. We endorse the recommendation contained in the 2008 report of the Royal Commission on Environmental Pollution that more attention should be paid to toxicology training. We welcome, therefore, the Government's commitment to tackling the shortage of trained toxicologists and ecotoxicologists and also their commissioning of an evaluation of the United Kingdom skills base for toxicologists and ecotoxicologists. However, the policies to address the shortfall promised for this year have not yet been launched. We look for urgent progress on this issue and ask that the Government update the Committee on its activity in this area (paragraph 4.52).

The Government accepts this recommendation. The Government is committed to tackling the shortage of trained toxicologists and work is ongoing in this important area.

The Medical Research Council (MRC) is investing £3M in supporting the Integrative Toxicology Training Partnership (ITTP), which is managed by the MRC Toxicology Unit at University of Leicester. This initiative will build capacity in integrative toxicology research through the award of approximately 25 PhD studentships to UK Universities.

The MRC ITTP initiative was established in 2007 and is currently in its third round of funding for PhD studentships in Toxicology. The emphasis is currently on aligning modern, cutting edge approaches, such as cell, molecular or systems biology with the toxicological sciences. Collaborative partnerships between universities and other relevant organisations, including industry and Government agencies, are being encouraged. Another priority of the MRC ITTP initiative is bringing innovative concepts and approaches from fields traditionally not considered to be associated with toxicology.

The MRC ITTP will support initiative partnerships between academia, industry and government to build expertise in toxicology and related disciplines that will help ensure the safe and effective development of drugs, chemicals and consumer products, and provide better assessment of risk deriving from environmental exposure.

In December 2009 the Government established an Industry and Higher Education Forum for Life Sciences to ensure the UK's skill needs for life scientists and clinicians are met. As a priority, the Forum will deliver activities to ensure STEM graduates, predominately those studying biological sciences at undergraduate, post-graduate and doctoral level, gain skills and knowledge of *in vivo* sciences (*in vivo* pharmacology, pathology, *in vivo* toxicology and physiology) and clinical pharmacology. In preparation for the Forum's activities, the Office for Life Sciences commissioned two task and finish teams to develop measures to address

these skills gaps. The Forum is due to hear from both teams in February 2010, and will agree how to deliver the recommendations. It is anticipated that the first phase of delivery will take place throughout 2010.

These initiatives are further supported by the underpinning work within BIS on the UK Science and Society strategy. This has key objectives to encourage greater awareness of science, technology, engineering and mathematics (STEM) careers, and to promote opportunities to engage with science and technology more generally. Independent expert groups on pre-19 science education, careers and public engagement with the sciences, intend to publish their reports and action plans in spring 2010. Major Government programmes, including STEMNET, STEM Ambassadors, the STEM Programme (a joint BIS-DCSF activity), and the 'Science: [So what? So everything]' campaign continue to encourage young people to consider the relevance of STEM to their lives and career prospects. Over time, these initiatives will significantly improve the availability of skills in many specialist disciplines, including toxicology.

Recommendation 9. We recommend that the Government work more closely with other EU Member States on research related to the health and safety risks of nanomaterials to ensure that knowledge gaps are quickly filled without duplication of effort, while continuing to support coordinated research in this area at an international level through appropriate international organisations including the International Organization for Standardization and Organisation for Economic Cooperation and Development (paragraph 4.60).

The Government accepts this recommendation. The report rightly highlights the essential international collaboration which is already taking place though the OECD. In addition to the projects described in the report there is significant Research Council support through PROSPEcT, a flagship £3.7M project on nanomaterials safety that is contributing to the OECD Working Party on Manufactured Nanomaterials Sponsorship Programme.

PROSPEcT will investigate the environmental toxicology, environmental fate, and physicochemical characterisation of zinc oxide and cerium oxide nanoparticles, and develop detection technologies and (in gaseous and liquid media) detector prototypes. It will provide crucial data to the OECD work, by addressing gaps in the current level of knowledge on the physico-chemical and (eco)toxicological properties of these materials, followed by fundamental scientific research leading to establishing scientific test methodologies to study those endpoints that may not be assessed through standard tests used for bulk chemicals (i.e. not in nano form).

The project will develop generic protocols that will contribute to potential risk assessments to be conducted on those products that contain the particles that form the basis for the project, whilst providing data that might allow for the use of approximation tools and model systems to assess the risk of other, similar particles.

The Research Councils will continue to support coordinated EU and international nanotechnology research through organisations such the OECD.

Within the EU, the UK has supported the inclusion of opportunities for collaborative R&D in nanosafety and nanotoxicology in the Work Programmes of the Nanosciences,

Nanotechnologies, Materials and New Production technologies (NMP) theme of the co-operation programme of the 7th research framework programme. The emerging strategy for the nanotechnology aspect of the theme includes ensuring the safety of nanotechnology. Co-ordination of Member States' own activities in this area has been strengthened by the launching of a call for an ERA-Net in last year's NMP Work Programme. The UK has taken a leading role in developing a proposal to establish such an ERA-Net.

The European Commission has conducted an on-line consultation on the content of a European Nanotechnology Action Plan 2010-2015. The Government's contribution to the consultation has been through submitting UK strategy documents on nanotechnology.

Recommendation 10. We recommend that the Food Standards Agency develop, in collaboration with the food industry, a confidential database of information about nanomaterials being researched within the food sector to inform the development of appropriate risk assessment procedures, and to aid in the prioritisation of appropriate research. Industry participation in this database should be mandatory, given the failure of similar voluntary schemes in the United Kingdom and elsewhere (paragraph 4.72).

The Food Standards Agency agrees that horizon scanning and information about current and future technological developments are essential, for the reasons set out in the report. It is inevitable that businesses will be wary of releasing information about their research, even to a Government Department, where that information is commercially sensitive and of value to their competitors. However, while a mandatory reporting requirement for food-related research would ensure that information is provided, it could also act as a deterrent for companies and other laboratories to carry out research and development in the UK, if they could avoid any reporting requirement by transferring this work to other jurisdictions.

It seems doubtful whether existing legal powers could be used to compel UK food companies to provide information about their research activities or their plans for future product launches. Introducing a mandatory reporting system would therefore require new legislation.

The Food Standards Agency recognises the importance of gathering intelligence about future developments in the food sector, in order to identify and respond to emerging risks. In recent years, the Agency has commissioned projects looking at likely developments in the use of nanotechnologies (in food and in food contact materials) and at food innovation more generally. In December 2009 the Agency published its Strategic Plan for 2010-2015, which identifies as a strategic priority the need to increase horizon scanning and intelligence on global food supply. The Agency is currently developing a programme of work in this area, including the developments of appropriate databases.

The Food Standards Agency will therefore include applications of nanotechnologies in its work on emerging risks, through intelligence gathering and engagement with industry experts in order to obtain information about likely developments, in order to ensure that regulations and risk assessment approaches can deal adequately with future products.

As set out in the UK Nanotechnologies Strategy (Actions 4.8 and 4.9), the Agency will collaborate with other Government Departments and the Nanotechnologies Collaboration Group to develop a scheme to collect information on nanomaterials in general.

Regulatory Coverage

Definition of nanotechnologies and nanomaterials

Recommendation 11. Given the uncertainty about the potential risks of nanomaterials, it is essential that any nanomaterial used in a food product (with the exceptions set out in paragraph 5.32) should to be subject to a formal risk assessment process through the European Food Safety Authority. We recommend, therefore, that the Government should work within the European Union to promote the amendment of current legislation to ensure that all nanomaterials used in food products, additives or supplements fall within the scope of current legislation. We recommend in particular that the legislation should, for the avoidance of uncertainty, include workable definitions of nanomaterials and related concepts (paragraph 5.19).

The Government accepts this recommendation and notes that relevant amendments are in progress in a number of legislative areas. In June 2009 the Council of the European Union reached political agreement on a proposal to amend the Novel Food Regulation. One of the aims of the amended proposal is to clarify that food containing or consisting of engineered nanomaterials will fall within the scope of the Novel Foods Regulation and will therefore require mandatory pre-market safety assessment and approval before being marketed in the EU. The amended proposal highlights the importance of a uniform definition for engineered nanomaterials and proposes that the EU endeavours to reach an agreement on a definition. The UK is working actively in collaboration with the Commission and other Member States in monitoring amendments to the proposed definition with the aim of improving clarity and enforceability. Additionally, in view of the various definitions of nanomaterials published by different bodies at international level and the constant technical and scientific developments in the field of nanotechnologies, the proposal specifically allows the definition to be adapted and amended as necessary following its adoption.

New EU legislation on food additives (Article 12 of Regulation (EC) No 1333/2008) came into effect on 20 January 2010 and states that:

> "*When a food additive is already included in a Community list and there is a significant change in its production methods or in the starting materials used, or there is a change in particle size, for example through nanotechnology, the food additive prepared by those new methods or materials shall be considered as a different additive and a new entry in the Community lists or a change in the specifications shall be required before it can be placed on the market*".

The current draft of the Plastic Implementing Measure (consolidated legislation on food contact plastics), if adopted, will set the precedent for nanomaterials in food contact materials:

> *"Unless explicitly mentioned in the specifications in Annex I the use of substances in nanoform shall not be authorised."*

***Recommendation* 12.** We recommend that the Government should work towards ensuring that any regulatory definition of nanomaterials proposed at a European level, in particular in the Novel Foods Regulation, should not include a size limit of 100nm but instead refer to 'the nanoscale' to ensure that all materials with a dimension under 1000nm are considered. A change in functionality, meaning how a substance interacts with the body, should be the factor that distinguishes a nanomaterial from its larger form within the nanoscale (paragraph 5.24).

The Government agrees with the recommendation that a clear regulatory definition for nanomaterials should be pursued, one that encompasses all relevant aspects of the material and is not limited to a specific size range.

As stated above (recommendation 11), the Food Standards Agency is working with the Commission and other Member States on a revision of the Novel Foods Regulation and amendment of the proposed definition. Although this definition is currently under review, it does already make reference to engineered nanomaterials including structures, agglomerates or aggregates, which may have a size above the order of 100 nm but retain properties that are characteristic to the nanoscale.

However, it is important to note that the definition that is being proposed for inclusion in the Novel Foods Regulation is a safety net, since the majority of nanomaterials are covered by other parts of the definition of "novel food". The existing definitions ensure that foods fall within the scope of the legislation if they are produced using a new production technology which alters their properties, such as nutritional value or metabolism. This should be sufficient to ensure that foods produced using new technologies for which there is a change in functionality will be assessed under this Regulation, irrespective of the particle size. The amended proposal further highlights that emerging technologies in food production processes (including food(s) consisting of engineered nanomaterials) which have an impact on food or food safety will fall within the remit of the Novel Foods Regulation.

From the perspective of food contact materials, the FSA will take to the Commission the position adopted by the Government, but the current terminology in the draft Plastic Implementing Measure (see Recommendation 11 above) is already in line with the report's recommendation: "New technologies that engineer substances in particle size that exhibit chemical and physical properties that significantly differ from those at a larger scale, for example, nanoparticles, should be assessed on a case-by-case basis as regards their risk until more information is known about such new technology." It is only after such assessment that they would be placed in Annex I.

Recommendation 13. We recommend that Government should work within the European Union to clarify the phrase "properties that are characteristic to the nanoscale" through the inclusion in the Novel Foods Regulation of a more detailed list of what these properties comprise. This list should be regularly reviewed, as the understanding of nanomaterials develops, to ensure it provides comprehensive and up-to-date coverage of relevant properties (paragraph 5.26).

Article 3(4) of the amended proposal states that the European Commission can adopt implementing measures to clarify the definition for engineered nanomaterials (see Article 3(2)(c)). Given the importance attached to this phrase, and the broader definition of engineered nanomaterials, the UK will be encouraging the Commission to provide this

additional clarification as soon as possible, and before the date of application of the new regulation.

From a food contact materials perspective, we understand that it is already agreed within the Commission that definitions should be harmonised across legislative areas. The Commission has not yet included a definition of nanomaterials but the draft Plastic Implementing Measure referred to in Recommendations 11 and 12 above gives useful references and indicates the Commisison's thinking, which is in line with the views expressed in the Select Committee's report.

Recommendation 14. We recommend that, for regulatory purposes, any definition of 'nanomaterials' should exclude those created from natural food substances, except for nanomaterials that have been deliberately chosen or engineered to take advantage of their nanoscale properties. The fact that they have been chosen for their novel properties indicates that they may pose novel risks (paragraph 5.32).

The Government agrees with the principle that nanomaterials created from natural food substances should be excluded from the definition, unless engineered or specifically chosen for their nanoscale properties.

The definition of nanomaterial that is currently being discussed for inclusion in an updated regulation on novel foods (see Recommendation 11 above) makes specific reference to "engineered" nanomaterials. Other nanomaterials created from natural food substances would therefore be excluded from the scope of this part of the Regulation. Such products could, however, still meet the definition of "novel food" if they are the result of new processes that significantly alter their properties.

Distribution of particle size

Recommendation 15. We recommend that the Government ensure that implementation guidelines for legislation state clearly what proportion of a bulk material has to be at the nanoscale for regulatory oversight to be triggered (paragraph 5.33).

The Government agrees that the limits for the proportion of a bulk material that would trigger regulatory oversight should be clarified, subject to the availability of analytical methods to determine such proportions. Ideally this should be set out in common EU-wide guidance but if this is not possible the Food Standards Agency will address it at national level.

Next generation nanomaterials

Recommendation 16. Given the pace at which novel technologies develop we recommend that, in addition to its on-going monitoring of the state of the science, the Food Standards Agency should formally review the suitability of legislation every three years to ensure that regulatory oversight and risk assessment keeps pace with the development of these technologies (paragraph 5.34).

The Food Standards Agency has reviewed the relevant legislation and published the findings of this review in August 2008, when no major gaps in legislation relating to nanotechnologies were found. The Agency agrees that regulation and risk assessment need to keep pace with scientific and technological developments and that the suitability of

legislation should be reviewed at regular intervals, which may be shorter (or longer) than every three years. In particular, the revised EU proposal for a new regulation on novel foods includes a mechanism for speedily updating the definition of "engineered nanomaterial" and this will be subject to on-going review. The Food Standards Agency will report on progress with the regulation of nanomaterials in regular updates to the discussion group (see recommendation 32 below).

REACH

Recommendation 17. We welcome the Government's decision, in response to the Royal Commission on Environmental Pollution's report, to recognise that functionality, as well as size, should be the focus of required revisions to REACH (paragraph 5.36).

Recommendation 18. We commend the Government's commitment to address the issue of the one–tonne threshold for considering the potential toxic effects of substances under the REACH Regulations. We ask the Government to update the Committee on the progress they have made towards meeting this urgent need (paragraph 5.37).

The Government continues to support the European Commission's view that the REACH Regulation applies to nanomaterials and we believe that REACH, alongside more specific legislation, such as workplace legislation and the Classification, Labelling and Packaging Regulation, provides the most sensible legislative framework for the regulation of nanomaterials. However, we recognise that some aspects of REACH were not designed with nanomaterials in mind and may give rise to implementation issues.

The European Commission's Competent Authority Subgroup on Nanotechnologies (CASG-Nano) has been established to exchange views on existing and arising implementation issues and other matters in relation to nanomaterials under REACH. The Government continues to engage actively in this process, through the UK Health and Safety Executive.

One issue, as highlighted by the Select Committee, is whether the one-tonne threshold for REACH registration will allow the capture of information about nanomaterials. Nanomaterials produced or imported in amounts greater than one tonne per year will need to be registered. So will nanomaterials which are produced or imported alongside bulk forms of the substance, where the substance – in all its forms – meets the registration threshold. The first deadline for registration of qualifying substances under REACH is 30 November 2010. It is expected that this first tranche of registrations will provide information on some nanomaterials, for example, where they have bulk forms produced or imported in volumes greater than 1000 tonnes per year, or where they are classified as meeting certain hazard criteria. Further REACH registration deadlines will follow in June 2013 and June 2018.

Alongside REACH registration, the Government intends to develop a scheme to collect information on both nanomaterials and products containing nanomaterials that are available in the UK (Action 4.8 in the UK Nanotechnologies Strategy). This bottom-up approach could enable comparison with data received through REACH, in turn informing the Government's view on the potential need for further measures or revisions to REACH.

Self-regulation

Recommendation 19. We recommend that the Government, in collaboration with relevant stakeholders, support the development of voluntary codes of conduct for nanotechnologies in order to assist the continuing development of effective legislation for this rapidly emerging technology. The Government should work to ensure that voluntary codes are of a high standard, are subject to effective monitoring processes and are transparent (paragraph 5.42).

The Technology Strategy Board has supported the development of a nanotechnology code through its funding of the Nanotechnology Industry Association (NIA) and the Nanotechnology Knowledge Transfer Network (NanoKTN). Both NanoKTN and NIA were co-sponsors of the NanoCode together with the Royal Society and Insight Investment. The Knowledge Transfer Networks that have an involvement in nanotechnology will be promoting the adoption of the NanoCode to companies in their sector.

Regulatory Enforcement

Risk Assessment

Recommendation 20. We endorse the case-by-case approach taken by the European Food Safety Authority in assessing the safety of products. It allows the responsible development of low-risk products where safety data are available and is, in effect, a selective moratorium on products where safety data are not available. It provides consumers with the greatest security and ensures that unless a product can be fully safety assessed, on its own merits, it will not be allowed on to the market (paragraph 6.12).

The Government notes that the European Food Safety Authority, having recently completed its review of nanoscience and nanotechnologies in relation to food and feed safety, has recently begun work on a guidance document for risk assessment of nanomaterials, which will provide practical recommendations on how to assess applications from industry to use engineered nanomaterials in food additives, enzymes, flavourings, food contact materials, novel foods, food supplements, feed additives and pesticides. The proposed guidance document, a first draft of which is due to be completed by July 2010, will be subject to public consultation prior to being finalised.

Recommendation 21. We welcome the participation of the Food Standards Agency in a European Union project which will investigate methods for detecting and measuring nanomaterials in the food. Ensuring that this research results in practical tests that can be used by enforcement agents will be an important step in securing the safety of food imports (paragraph 6.15).

The "NANOLYSE" project began in January 2010. It is being carried out by a consortium of institutes in different European countries and will run for 3 years. The project is part of the seventh Framework Programme for European research and will be overseen by the European Commission, which is providing the majority of the funding. The Food Standards Agency is co-funding the UK participant in the consortium, the Food and Environment Research Agency, which is leading on the analytical aspects of the project. The Food Standards Agency will keep close watch on the progress of this work and will ensure that it

has the maximum possible relevance to analytical methods that can be used for enforcement purposes.

Recommendation 22. We welcome the assurance from the Government that the Food Standards Agency will ensure that enforcement authorities are made aware of the issues surrounding the use of nanomaterials in imported food (paragraph 6.17).

Recommendation 23. We recommend that the Government should ensure that research into methods of measuring nanomaterials in food results in the development of practical tests for enforcement authorities to use on imported food, and develop a plan to inform and educate enforcement authorities once such tests have been developed (paragraph 6.17).

The Government accepts this recommendation. The project mentioned above (recommendation 21) will investigate possible approaches to detecting and characterising nanomaterials in food, and if successful this research will provide a basis for validated methods that can be used for enforcement purposes.

Guidance for companies

Recommendation 24. We recommend that the Government work with the European Food Safety Authority as it develops guidance on the implementation of the Novel Foods Regulation and other relevant legislation. We urge the Government to state what steps they will take to ensure industry and academia are involved in the development of this guidance (paragraph 6.21).

The Government accepts this recommendation. The European Food Safety Authority (EFSA) will be working with the European Commission to develop technical guidance for interested parties who wish to submit applications for novel foods (Article 12 of the amended proposal). As a first step, in November 2009, EFSA dedicated one of its Scientific Colloquia into looking at new and emerging issues in the novel food regulatory area. This colloquium was attended by FSA officials (who acted as rapporteurs) together with stakeholders from industry and academia and one of the key discussions centred on the data requirements to demonstrate the safety of foods derived by nanotechnology. In addition EFSA is currently developing guidance on the potential risks arising from applications of nanoscience and nanotechnologies to food, feed and pesticides and a UK government toxicologist sits on the working group carrying out this work.

EFSA will consult on both of these documents so UK Government will have the opportunity to comment when they are in draft form.

Recommendation 25. We recommend that the Government continue to push for continued international dialogue and information exchange on appropriate approaches to regulating the applications of nanotechnologies in the food sector, and seeks to ensure that all relevant international organisations are aware of the emerging implications of the development of nanotechnologies (paragraph 6.29).

The Government is committed to maintaining appropriate dialogue and information exchange with our global trading partners, and relevant international standard setting bodies, such as the Codex Alimentarius Commission. The UK will continue to work with EU

partners and the wider international community to develop necessary safeguards for the use of this emerging technology.

Recommendation 26. We recommend therefore that the Food Standards Agency create and maintain an accessible list of publicly-available food and food packaging products containing nanomaterials that have been approved by the European Food Safety Authority (paragraph 6.37).

The Food Standards Agency accepts this recommendation and agrees that there are benefits in setting up a publicly accessible register of available food and food packaging products containing nanomaterials. As the report points out, one problem with such a list will be the criteria for inclusion. Rather than limit the list to those nanomaterials that have been evaluated by the European Food Safety Authority, there may also be value in providing public information about materials that may, rightly or wrongly, appear to have nanoscale elements. The Food Standards Agency will engage with the discussion group (see Recommendation 32 below) to determine how such a list can be established and maintained.

This activity will be carried out alongside the general scheme described in Actions 4.8 and 4.9 in the UK Nanotechnologies Strategy, which relates to general products containing nanotechnologies.

Effective Communication

Current public attitudes to the use of nanotechnologies

Recommendation 27. We recommend that the Government commission a survey of public attitudes towards the use of nanotechnologies in the food sector, with the aim of informing debate on the subject. This work should be carried out regularly to keep pace with evolving public opinion (paragraph 7.10).

The Government agrees that public attitudes are a critical factor in the success of innovations, particularly in the food sector, and that public attitudes should be kept under review. The Food Standards Agency has stated that it will include nanotechnologies in its programme of citizens forums during 2010, in order to gain a better understanding of what the public know about nanotechnology and how they see its potential in relation to food. This type of deliberative public engagement is a distinctive approach to involving people in decision-making. It provides policy and decision makers with rich data on public attitudes and values, offers opportunities to fully explore why people feel the way they do, and allows the time to develop public understanding, ideas, options and priorities with the public. For the public participants, the experience provides opportunities to share and develop their views with each other and directly with experts and decision-makers.

The outcome of these consumer forums could also help with the design of quantitative surveys of the general public in future. However, it is unlikely that such surveys would yield useful data at present, as most people have only a low awareness and understanding of nanotechnologies.

Communication

Recommendation 28. We welcome the Government's decision to commission a website designed to give the public a balanced source of information on nanotechnologies, and commend the decision to include a section specifically covering issues related to the use of nanotechnologies in the food sector (paragraph 7.14).

The need for a permanent consumer focussed site about nanotechnologies is discussed in paragraphs 85-87 of the UK Nanotechnologies Strategy.

Recommendation 29. We recommend that the Government work with the food industry to secure more openness and transparency about their research and development and their future plans for the application of nanotechnologies in the food sector (paragraph 7.19).

The Government agrees that a lack of openness, or even a perceived lack of openness, will act to undermine public confidence in innovative products and new technologies. The Food Standards Agency will therefore work with industry and other stakeholders to ensure that as much information as possible is shared, for example through the discussion group (Recommendation 32) and through a public list of products containing nanomaterials (Recommendation 26).

Recommendation 30. Consumers can expect to have access to information about the food they eat. But blanket labelling of nanomaterials on packages is not, in our view, the right approach to providing information about the application of nanotechnologies. We believe the primary mechanism should be a public register of foods containing nanomaterials, as we have recommended in Chapter 6 above. We urge also that the Government, along with consumer groups, should consider other means through which this information can be made available and accessible to consumers (paragraph 7.24).

The Government accepts this recommendation, which will be taken forward by the Food Standards Agency and the discussion group (see recommendation 32), in the light of the future decision on establishment of a permanent consumer focussed site about nanotechnologies (see recommendation 28).

Public engagement

Recommendation 31. We agree with the Royal Commission on Environmental Pollution that the Nanotechnologies Stakeholder Forum provides a useful model on which to base a public engagement group to discuss the issues surrounding the use of nanotechnologies in the food sector (paragraph 7.29).

Recommendation 32. We recommend that the Government should establish an open discussion group, along the lines of the DEFRA-sponsored Nanotechnology Stakeholder Forum, to discuss issues surrounding the application of nanotechnologies in the food sector. This group should contain representatives from Government, academia and industry, as well as from representatives groups from the public such as consumer groups and nongovernmental organisations. Meetings should take place on a regular basis as nanotechnology applications are developed and enter the United Kingdom food market. The Government should ensure that concerns of, and suggestions made by, the group are published and taken into account in policy decision-making processes. The Government should report on how these concerns are being met at regular intervals (paragraph 7.31).

The Government accepts this recommendation and agrees that it would be valuable to discuss the application of nanotechnologies in the food sector with the relevant stakeholders, in addition to the arrangements for involving stakeholders in nanotechnologies more generally. The Food Standards Agency will take this forward, ensuring that records of this discussion group and the associated papers are published. The Agency will report back to the group on actions and decisions that have been taken and how these take account of the views expressed by the group.

This group will complement the Nanotechnologies Collaboration Group that is being established by GO-Science, in collaboration with Defra, and which will facilitate communication and collaboration on nanotechnologies in general (Action 5.1 in the UK Nanotechnologies Strategy).

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